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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,754	09/10/2001	Caroline Boursaux-Eude	03495.0206	8881

7590 05/23/2003

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
1300 I STREET, N.W.
WASHINGTON, DC 20005-3315

EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/23/2003 17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/855,754	Boursaux-Eude et al
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *56-114* is/are pending in the application.

4a) Of the above, claim(s) *62-77, 81, 83, 85-88, and 95-97* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *56-61, 78-80, 82, 84, 89-94, and 98-114* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *11 & 12*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 56-61, 78-80, 82, 84, and 89-94 in Paper No. 14, received November 15, 2002 is acknowledged. Additionally, Applicants have added new claims 98-114. The traversal is on the ground(s) that Groups I-III claim a composition which comprises "at least one of" pertactins of Bordetella bronchiseptica, Bordetella parapertussis and Bordetella pertussis. Applicants arguments are persuasive. Accordingly Groups I-III, claims 56-61, 78-80, 82, 84 and 89-94 will be examined in their entirety. The requirement to a single sequence is also accordingly withdrawn. The restriction requirement of groups IV-XIV has not been traversed and is still deemed appropriate and maintained.

Accordingly, claims 56-114 are pending in the instant application of which claims 62-77, 81, 83, 85-88 and 95-97 are withdrawn from further consideration.

This requirement is still deemed appropriate and accordingly made FINAL.

Claim Objections

2. Claims 89-94 and 109-114 are objected to because of the following informalities: Each of claims 89-94 and 109-114 recite numerous abbreviations. Identical abbreviations can represent vastly different compounds, e.g. DNT = dermonecrotic toxin or dinitro toluene. Accordingly,

Applicant is required to recite the full length name of each abbreviation the first time it occurs in the claims. Appropriate correction is required.

3. Claims 89-94 and 109-114 are objected to because of the following informalities: Each of claims 89-94 and 109-114 recite "where in the adhesin." The obvious typographical error should recite "wherein the adhesin..." Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 82 and 84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition, does not reasonably provide enablement for a pharmaceutical composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification provides insufficient guidance of how to use the claimed polypeptides as a pharmaceutical for the prevention of disease. It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A et al.,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that

protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen."

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the proteins of undefined structure encompassed in the scope of the claims one skilled in the art would be forced into undue experimentation in order to practice broadly the claimed invention.

As a suggestion, amendment of the claims to recite "An immunogenic composition..." will be sufficient to overcome this rejection.

5. Claims 56-61, 78-80, 82, 84, 89-94, and 98-114 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 56-61, 78-80, 82, 84, 89-94, and 98-114 recite an immunogenic composition comprising a mixture of pertactins of Bordetella species, fragments and variants thereof.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between

genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the fragment of the pertactin represented by SEQ ID NO: 8 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by SEQ ID NO: 8 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. It is further noted that SEQ ID NO: 8 is not a full length protein, given that the classical start codon, methionine, is absent.. Given that the function of the non-full length protein is not set forth, the written description of the instant application is supportive of only an antigenic peptide consisting of SEQ ID NO: 8, since additional amino acids on the N-terminus or C-terminus will have a profound impact on the activity of the protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 56-61, 78-80, 82, 84, and 98-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles et al.

The claims are drawn to an immunogenic composition comprising a mixture of pertactins of Bordetella species, fragments and variants thereof, wherein the composition comprises at least one of: pertactins of B. bronchiseptica, pertactins of B. parapertussis; and pertactins of B. pertussis, in amounts sufficient to induce a humoral or cellular immune response against at least one of B. bronchiseptica; B. parapertussis and B. pertussis; in an animal to which the immunogenic composition is administered.

Charles et al (WO 92/11292) disclose of the isolation of a pertactin from Bordetella, as well as its incorporation into a vaccine. Charles et al further disclose that the vaccine may optionally contain additional antigens of B. parapertussis or other bacteria, such as B. pertussis, tetanus and diphtheria. (See abstract and page 8). The protein disclosed by Charles et al is structurally identical to the recited limitations of the claims in that the protein comprises a

repeating GGXXP Region I (SEQ ID NO: 25 of the instantly filed invention), and a repeating PQP Region II.

In view that Charles et al disclose of a vaccine comprising a pertactin isolated from Bordetella in combination with other additional antigens of B. parapertussis or other bacteria, such as B. pertussis, tetanus and diphtheria, the disclosure of Charles et al is deemed to anticipate the claimed invention.

7. Claims 56-61, 78-80, 82, 84, and 98-108 are rejected under 35 U.S.C. 102(b) as being anticipated by Clare et al.

The claims are drawn to an immunogenic composition comprising a mixture of pertactins of Bordetella species, fragments and variants thereof, wherein the composition comprises at least one of: pertactins of B. bronchiseptica, pertactins of B. parapertussis; and pertactins of B. pertussis, in amounts sufficient to induce a humoral or cellular immune response against at least one of B. bronchiseptica; B. parapertussis and B. pertussis; in an animal to which the immunogenic composition is administered.

Clare et al (WO 91/15571) disclose of a vaccine comprising a pertactin (P 69) in association with a toxoid and PBS. (See abstract and page 15). The protein disclosed by Clare et al is structurally identical to the recited limitations of the claims in that the protein comprises a

repeating GGXXP Region I (SEQ ID NO: 25 of the instantly filed invention), and a repeating PQP Region II. The protein further comprises SEQ ID NO: 8 of the instantly filed invention.

In view that Clare et al disclose of a vaccine comprising a pertactin isolated from Bordetella in combination with other additional antigens, the disclosure of Charles et al is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 56-61, 78-80, 82, 84, 89-94, and 98-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charles et al or Clare et al in view of Gueirard et al.

The claims are drawn to an immunogenic composition comprising a mixture of pertactins of Bordetella species, fragments and variants thereof, wherein the composition comprises at least one of: pertactins of B. bronchiseptica, pertactins of B. parapertussis; and pertactins of B. pertussis, in amounts sufficient to induce a humoral or cellular immune response against at least one of B. bronchiseptica; B. parapertussis and B. pertussis; in an animal to which the immunogenic composition is administered, wherein the composition further comprises at least one adhesin of Bordetella and a toxin of Bordetella, wherein the adhesin is selected from at least one of FHA, AGG2, AGG3 and the toxin is selected from at least one of PTX, DNT, TCT, and Ac-Hly.

The teaching of Charles et al and Clare et al are set forth above.

Neither Charles et al nor Clare et al teach of an adhesin selected from at least one of FHA, AGG2, AGG3 or a the toxin selected from at least one of PTX, DNT, TCT, and Ac-Hly.

Gueirard et al (US Patent Number 6,387,377) teach of published results showing that the acellular vaccines bivalent (PTX, FHA) induce very few side effects, is immunogenic and is efficacious against the disease (according to WHO definition). (See column 5).

Given that 1) Charles et al and Clare et al have taught of vaccines comprising a pertactin isolated from Bordetella in association with other bacterial antigens, and that 2) Gueirard et al

teach that a bivalent acellular vaccine of PTX and FHA is efficacious against the disease, it would have been prima facie obvious to have incorporated the PTX and FHA as taught by Gueirard et al with the pertactin as taught by Charles et al and Clare et al. The courts have held that when two separate agents are taught in the prior art to be useful for the same purpose it is obvious to combine the separate agents to form a third composition that is to be used for the very same purpose. (See In re Kerkhoven 676 F. 2d 846, 205 USPQ 1069 CCPA 1980).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

May 15, 2003